

## **DETAILED ACTION**

### ***Election/Restrictions***

This application contains claims 3, 4 and 6-13 drawn to inventions nonelected with traverse in the reply filed on 5/9/2005. A complete reply to the final rejection must include cancellation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

### ***Response to Amendment***

Applicants' amendments to claims 1, 2 and 14-16 have obviated the grounds of rejection of these claims under 35 USC 112, second paragraph. However, the amendment to claim 1 has necessitated the following new grounds of rejection:

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

**Claims 1, 2, 5 and 14-16 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement.** The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Applicants have amended claim 1 such that step b) recites "determining the proportion of CD45+ cells which are CD4+ lymphocytes using fluorescence measurement by:

- (i) establishing a primary discriminator to discriminate CD45+ cells of interest;

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- (ii) establishing a secondary discriminator, within said primary discriminator to discriminate CD4+ lymphocytes having CD<sup>Bright</sup>/low side scatter expression; and
- (iii) calculating the proportion of CD45+ cells which are CD4+ lymphocytes".

With regards to the recitation of a primary and secondary "discriminator(s)" there is found to be insufficient support in the disclosure as originally filed for this limitation; thus it is being considered new matter. The disclosure as originally filed only supports establishment of a primary and secondary gate(s), which would be the appropriate terminology used with flow cytometry. The only reference found in the specification to generic "discriminators" or discrimination is found in reference to size discrimination of cells (e.g. at Pg. 7, ln 29).

An amendment to the claims or the addition of a new claim must be supported by the description of the invention in the application as filed. In re Wright, 866 F.2d 422, 9 USPQ2d 1649 (Fed. Cir. 1989). Applicant is required to cancel the new matter in the reply to this Office Action.

### ***Conclusion***

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

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the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to ALLISON M. FORD whose telephone number is (571)272-2936. The examiner can normally be reached on 8:00-6 M-Th.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn can be reached on 571-272-0926. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Leon B Lankford Jr/  
Primary Examiner, Art Unit 1651